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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,231	01/18/2001	Deborah J. Phippard	3221-US	7382

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EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/765,231	**Applicant(s)** PHIPPARD ET AL.	
	Examiner Richard Schnizer, Ph. D	**Art Unit** 1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 February 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,5-7,11,18 and 29*.
   Claim(s) withdrawn from consideration: *32-48*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attached.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Applicant's arguments are unpersuasive. Enablement of the use of the claimed polynucleotides as diagnostics for OA, for drug development, or for therapy, depends on the establishment of a relationship between OA and the polynucleotides. There is no clear relationship between SEQ ID NO:53 and OA because although the specification teaches that SEQ ID NO:53 was preferentially observed in OA patients relative to controls, it remains unclear what is meant by "preferentially observed", and the specification does not disclose sufficient data for one to determine what "preferentially observed" might mean. As a result, the relationship between OA and SEQ ID NO:58 is unclear. For example, "preferentially observed" could mean that SEQ ID NO:58 was never observed in the non-OA libraries, or it could mean that a SEQ ID NO:58 was simply observed less frequently in the non-OA libraries. No data is presented regarding the relative amounts of SEQ ID NO:58 in OA versus non-OA tissues. This is an important point because in order to use SEQ ID NO:58 as a diagnostic one must obviously know what level of expression of SEQ ID NO:58 is diagnostic of OA. At pages 9 and 10 of the response Applicant argues that one of skill in the art would understand what is meant by "preferentially observed" and could use the claimed nucleifc acids as diagnostic for OA because one of skill in the art would know that significance levels of any sample size can be determined using appropriate statistical methods such as Student's T test. One of skill could therefore determine which patients had a statistically significant expression level of SEQ ID NO:53 relative to controls. This is unpersuasive because it assumes without support that statistically significant results were, or will be, obtained. There is no evidence of record to support a statistically significant correlation between OA and SEQ ID NO:53. Furthermore, Applicant assumes without support that ANY statistically significant deviation from control levels of SEQ ID NO:53 will be diagnostic of OA. In fact, even if SEQ ID NO:53 were diagnostic, and there is no significant evidence that it is, the expression level that correlates with disease may be 4 or 5 fold above controls, while a two fold increase may not correlate with pathology. The specfication provides no guidance as to what level of expression of SEQ ID NO:58 is diagnostic of OA. As a result one of skill in the art is left to perform this determination on his own, after first demonstrating a relationship between OA and SEQ ID NIO:53. This experimentation is undue because the diagnostic expression level is a critical piece of information required to use the invention, as intended. Another missing piece of critical information is the establishment of a significant relationship between SEQ ID NO:53 and OA. Failure to disclose this critical information results in a failure to meet the enablement requirement. See MPEP 608.01(p). Finally, Applicant's argument that the instant claims are composition claims and not method claims is unpersuasive because the basis of the rejection is that the specification fails to teach how to use the composition, and so fails to meet the enablement requirement.

DAVE TRONG NGUYEN
PRIMARY EXAMINER